prevent
valproate pregnancy prevention programme

# Medication Safety Series: MSS 13

# Valproate Medicines Safety Measures including Pregnancy Prevention Programme

**NEVER prescribe valproate:**
- if there is child-bearing potential without a PPP in place
- for migraine or bipolar disorder in pregnancy

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

## Valproate Safety Measures

See Guide for Healthcare Professionals for full details

**Initiation:**
- Valproate should not be initiated in patients aged under 55 years unless two specialist prescribers* independently consider and document (using the forms linked in this alert) that there is no other effective or tolerated treatment, or that there are compelling reasons that the reproductive risks do not apply
- Valproate must not be prescribed to any woman or girl able to have children unless the conditions of the Pregnancy Prevention Programme (PPP) are followed.
- There is an absolute contraindication on use of valproate for bipolar disorder (and other non-epilepsy indications) during pregnancy.
- If a patient becomes pregnant, treatment with valproate must be discontinued and switched to another treatment.

**Annual review:**
- An annual review is required where there is child-bearing potential. The next annual review for the patient requires two specialist prescribers* to agree that continuation is appropriate, but subsequent reviews only require one.

**Patient & carer information:**
- Patient guides are available from Valproate – reproductive risks - GOV.UK. Record this on the Electronic Patient Record (EPR).
- Shared decision making (on initiation or review) with patients of child-bearing potential can be supported by Bipolar disorder: is valproate the right treatment for me?

***Specialist prescriber definition:** a prescriber working with TEWV that is experienced in managing patients with bipolar disorder. The second specialist prescriber can be a named representative following an MDT discussion. The named specialist prescribers **cannot** be a foundation doctor (or similar level doctor) and must be level 2 or above if a non-medical prescriber.

## Risk Acknowledgement Forms

The appropriate form** (below) must be downloaded, completed with the patient, and scanned / saved into the EPR. A copy must be given to the patient and sent to the GP. See second page for further advice.
- Female Patients: Risk Acknowledgement Form (New Starter & Review)
- Male Patients: New Starter Risk Acknowledgement Form

Each step on the form should be completed in full.
Allowed exemptions are in step 1 of the risk acknowledgment form.
***Please note these nationally required forms do not use inclusive gender language.*

## Specialist Prescriber Responsibilities

- Discuss the risks (on initiation and review) with the patient / responsible person and complete a Risk Acknowledgement Form (RAF) as above.
- Where the patient does not wish to sign the RAF this means that prescribing would not be considered safe or appropriate as it reflects that the risks are not able to be fully understood with appropriate actions.

Where there is childbearing potential:
- Exclude pregnancy (by a pregnancy test) before initiation
- Ensure the need to have, and comply with, highly effective contraception throughout the entire duration of treatment, is understood. See the supporting documentation for further information.
- Perform an **annual review** with the patient to assess continuing need and to complete a new risk acknowledgement form if prescribing continues.
- Review and switch treatment, within days of referral, if there is an unplanned pregnancy
- Review and switch treatment for patients planning to become pregnant
- Recording the key points of the discussion in electronic care record including completion of the Risk Acknowledgement form
- Where applicable for new patients: send a copy of the shared care document (DTV or NYY) to the GP with the transfer of prescribing request

## Prescribing Valproate: Dispensing Quantities

Unless there are exceptional circumstances, valproate-containing medicines must be dispensed (by community pharmacies & TEWV dispensaries) in the manufacturer's original full pack (tablets packs are 30 or 100).

Exceptional circumstances apply if an individual risk assessment is carried out (this should form part of the individual's safety summary) and would be appropriate in the following circumstances:
- **Discharge / Out-Patient Prescriptions:** where there is a risk of self-harm and it is appropriate to limit supplies (e.g. to 7 days). The prescription should be annotated *"risk assessment in place **please supply exact quantity** requested".* [If the prescription is not annotated the pharmacy are required to dispense the nearest full pack.]
- Valproate should not normally be supplied in a monitored dosage system (MDS) due to stability. If an MDS is essential a risk assessment must be in place and communicated to the dispensing pharmacy.

An individual risk assessment is not required for **self-admin in secure in-patient services or leave prescriptions.** These will be dispensed by TEWV dispensaries in exact quantities under an overarching risk assessment agreed by D&T.

## Supporting documentation

- MHRA Guidance with Materials and resources
- NHS Valproate bipolar disorder decision tool
- Contraception
- Drug Safety Update – February 2025 with infographics

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# Valproate Prescribing – Safety requirements

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## Female*

### Age > 55 years

Complete usual regular/annual treatment review.
Shared care does not apply

### Age from Menarche to 55 years

#### Existing valproate prescription

Permanent reason PREVENT does not apply e.g. hysterectomy

Complete usual regular/annual treatment review.
Shared care does not apply

Complete section 1 of ARAF

PREVENT applies – complete ARAF annually
(Shared care applies)
(2 specialists required for ALL new initiations & for first annual review after Jan 2024♦)

♦ National recommendation - all current patients to whom PREVENT applies should have one ARAF completed by 2 specialists

#### New / restarted valproate prescription

Complete section 1 of ARAF

PREVENT applies – complete ARAF annually
(Shared care applies)
(2 specialists required for ALL new initiations & for first annual review after Jan 2024♦)

♦ National recommendation - all current patients to whom PREVENT applies should have one ARAF completed by 2 specialists

## Male*

(of any age who may father children; shared care does not apply)

### Existing valproate prescription

Complete usual regular/ annual treatment review

Reproductive risks apply

Ensure patient is aware of the risks of fathering children whilst taking valproate: offer contraceptive advice for patient & female partner; refer for specialist advice if planning a family in next year & offer advice on sperm donation as appropriate.

● e.g. patient is permanently infertile

### New / restarted valproate prescription

#### Age > 55 years

Complete usual regular/ annual treatment review

Reproductive risks apply

Ensure patient is aware of the risks of fathering children whilst taking valproate: offer contraceptive advice for patient & female partner; refer for specialist advice if planning a family in next year & offer advice on sperm donation as appropriate.

● e.g. patient is permanently infertile

#### Age < 55 years

Complete section 1 of RAF

Reproductive risks DON'T apply● – save form in notes

Reproductive risks apply

Complete rest of RAF prior to prescribing (Agreed by 2 specialists)

*National literature uses the terms male & female.
The female algorithm also applies to trans-males
The male algorithm applies to anyone who can biologically father children

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# Medication Safety Series: MSS 13 [Pharmacy Appendix]

## Valproate Medicines Restrictions including Pregnancy Prevention Programme

## Prescribing Valproate: Dispensing Quantities

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## Clinical Pharmacy Team

**During in-patient stay:**

- Check if PPP is applicable; if yes
  - for **females**, identify date of last ARAF; add this, and date next due, as a note to the prescription on EPMA
  - for **males**, check information on risks of fathering children has been provided
- Establish whether the patient will be able to have full pack dispensing
- If packed down supplies are likely to be required, work with MDT to undertake a supplies risk assessment and add to patient's safety summary (a specific mention would also be required if valproate must be dispensed in a monitored dosage system)
- Mark EPMA with a valproate specific instruction [exact guidance to follow] indicating packed down supplies

**On discharge:**

- When prescribing or checking discharge prescription ensure it is annotated "risk assessment in place please supply exact quantity requested"

**Community teams / clozapine management:**

- Support MDT to:
  - Highlight exact quantity requirement on safety summary
  - Include "risk assessment in place please supply exact quantity requested" on FP10 prescription & clozapine prescriptions where necessary

## Dispensary

**Guidance applies regardless of age and gender**

See prescribing quantities information on page 1 (linked via button above).

**Exact quantities (exceptional circumstances)**

Supply exact quantities for leaves (unless an increase of up to 10% enables a full pack to be dispensed – e.g. 28 tablets and can be rounded to 30).

When a risk assessment is in place to support exact quantities, the dispenser should add a Rx Note to the valproate medicines in EMIS.

If the prescription or Rx Note on EMIS highlights that a risk assessment is in place, then supply exact quantities.

Note: an individual risk assessment is not required for self-admin in secure in-patient services or leave prescriptions.

**Full packs**

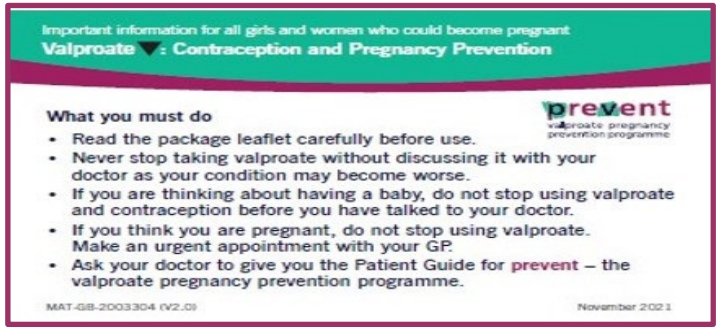
In all other circumstances supply full packs of valproate medicines (rounded up).

**Always supply:**

- A patient warning card*
- An information leaflet*

*for leaves: a card and leaflet only need to be supplied once for every dispensing episode (e.g. if 5x1 day leaves being prepared only the first issue needs a leaflet and card – the dispensing bag should be marked "supply first – contains leaflet")

Dispensing labels must not be placed over any warning labels/stickers on the medication box. In addition, do not cover key information on the packaging such as expiry or product details.


Important information for all girls and women who could become pregnant

Valproate : Contraception and Pregnancy Prevention

What you must do

- Read the package leaflet carefully before use.
- Never stop taking valproate without discussing it with your doctor as your condition may become worse.
- If you are thinking about having a baby, do not stop using valproate and contraception before you have talked to your doctor.
- If you think you are pregnant, do not stop using valproate. Make an urgent appointment with your GP.
- Ask your doctor to give you the Patient Guide for prevent – the valproate pregnancy prevention programme.

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Image of patient warning card

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